

# EXHIBIT “A”

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

<b>IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION</b>	) MDL No. 1456 ) Master File No. 01-12257-PBS ) ) (Matter to be taken under ) submission by the court)
<b>THIS DOCUMENT RELATES TO:</b>	)
<b>State of California, et al v. Abbott Laboratories et al</b>	)
<b>CASE #: 1:03-cv-11226-PBS</b>	) Judge Patti B. Saris

**THE STATE OF CALIFORNIA'S SUPPLEMENTAL BRIEF REGARDING**  
**THE ISSUE OF FEDERAL PREEMPTION OF REBATE CLAIMS**  
**INTRODUCTION**

The State of California and the Relator, Ven-A-Care of the Florida Keys, Inc., respectfully request that the Court consider the points raised in this brief with respect to the issue of whether a state's ability to pursue Medicaid fraud claims arising under the Medicaid Rebate Program has been pre-empted by Congress. Although California does not believe this point has been clearly stated before, the state is the recipient of all Medicaid Rebate payments, is the party immediately and directly injured by fraud in the area, is a party to the Medicaid Rebate Agreement with the drug manufacturers, and is required by federal law to prosecute Medicaid fraud actions. A finding that this area has been federally preempted will have far reaching affects that will severely impede the States' capacity to comply with their obligations under the Medicaid Program and will inhibit their ability to preserve and protect Medicaid Program funds vital to the care of their poor.

California's motion to dismiss its Medicaid rebate claims without prejudice, along with its

Motion to Remand, were heard before this court on December 12, 2003. The Court heard California's motion at the same time as it heard the motions to dismiss filed by defendants in the Montana and Nevada cases. Federal preemption over best price Medicaid rebate fraud claims was raised in the Montana and Nevada motions, but preemption was not the subject of any motion in the California case. However, during the hearing, the Court inquired about the effect on California's rebate claims and its pending motion to dismiss if the Court found that the best price rebate claims were preempted by federal law.

As the Court is aware, the complaint California served on defendants Abbott and Wyeth does not contain an allegation of rebate fraud. These allegations are only set forth in the sealed complaint. California has decided to dismiss the allegations of rebate fraud from that complaint without prejudice. California will not seek to raise those allegations in this case. However, if California determines that there are claims to be prosecuted it does intend to assert its claims of rebate fraud in a separate action.<sup>1</sup>

California contends that none of the rebate claims are preempted. However, during the December 12, 2003 hearing, the Court seemed to express particular concern that the confidentiality provisions of the rebate statute might indicate Congressional intent to preempt the states from bringing rebate claims that depended on the confidential information. The Court should be aware that the particular rebate claims alleged in California's sealed complaint are substantively different than the best price rebate claims the Court is considering in the Montana and Nevada cases and do not

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<sup>1</sup> Contrary to what may have been intimated by the California Attorney General's Office at the hearing on December 12, 2003, California does intend to reserve its rights to assert its claims of rebate fraud in a separate action, consistent with what it believes are its legitimate rights as a plaintiff in determining what claims to bring and in what court. California has no intention of turning its rebate fraud claims over to HHS.

directly involve the confidential information that was the concern of the Court.

With regard to the preemption issue on the best price rebate claims, as set forth in the Montana and Nevada motions, California urges this Court to find that there is no federal preemption over Medicaid rebate claims since the Medicaid statute expressly contemplates joint state and federal enforcement against Medicaid fraud.

I.

**MEDICAID REBATE CLAIMS ARE NOT PREEMPTED BY FEDERAL LAW**

Contrary to defendants' assertions in the Nevada and Montana cases, the rebate fraud claims are not preempted by federal law. In support of their preemption argument in the Nevada and Montana cases, defendants focus solely on the federal Rebate Statute, 42 U.S.C. § 1396r-8 and on their rebate agreements with the Secretary of Health and Human Services. Defendants ignore the fact that rebate fraud is Medicaid fraud and the rebate section of the Social Security Act does not exist in a vacuum. The entire statutory scheme must be considered to determine whether Congress intended to preempt state authority in the area of rebate fraud. The Social Security Act does not expressly state nor does it imply that the states may not prosecute rebate fraud. To the contrary, the Social Security Act expressly grants the states the right and the obligation to prosecute fraud in the Medicaid program. Specifically, 42 U.S.C. §1396b(q) requires that the states operate a Medicaid Fraud Control Unit with responsibility for "conducting a statewide program for the investigation and prosecution of violations of all applicable State laws regarding any and all aspects of fraud in connection with . . . any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan under this title." The federal statutory scheme that established the Medicaid program provides for a cooperative federal-state effort to combat fraud in the program, which includes

rebate fraud.

Medicaid is a cooperative state-federal program, in which each participating state designs and implements its own Medicaid program subject to certain strictures established by federal law. 42 U.S.C. §1396a (prescribing general requirements of state Medicaid plan); cf. Harris v. McRae, 448 U.S. 297, 309, 65 L. Ed. 2d 784, 100 S. Ct. 2671 (1980) (referring to the Medicaid program as a "system of 'cooperative federalism'" (quoting King v. Smith, 392 U.S. 309, 316, 20 L. Ed. 2d 1118, 88 S. Ct. 2128 (1968))). As such, we readily conclude that the categories of express preemption and implied preemption are inapplicable here.

Pharmaceutical Research and Manufacturers of America v. Meadows, 304 F.3d 1197, 1206 (11<sup>th</sup> Cir. 2002).

Medicaid is one of several cooperative state-federal programs covered by the Social Security Act, and the Supreme Court has suggested that preemption for these types of programs may be difficult to establish. In New York State Department of Social Services v. Dublino, 413 U.S. 405, 37 L. Ed. 2d 688, 93 S. Ct. 2507 (1973), the Court addressed whether a New York welfare reform statute preempted another provision of the Social Security Act. In upholding the New York law, the Supreme Court observed, "Where coordinate state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal pre-emption becomes a less persuasive one." Id. at 421 (reviewing possible preemption under the Federal Work Incentive Program). . . .

Pharmaceutical Research and Manufacturers of America v. Meadows, 304 F.3d at 1206. See also, New Mexico Dep't of Human Servs. v. Department of Health & Human Servs. Health Care Financing Admin., 4 F.3d 882, 886 (10th Cir. 1993); Wash. Dep't of Soc. & Health Servs. v. Bowen, 815 F.2d 549, 557 (9th Cir. 1987). This clearly indicates that the States have authority to pursue Medicaid rebate fraud, just as the federal government does.

Defendants contend that the rebate statute preempts the states from pursuing state claims for rebate fraud. However, during oral argument, defendants would not concede that the federal government had the authority to bring an action for rebate fraud on behalf of the states. Therefore, it appears defendants contend that no one can pursue claims of rebate fraud on behalf of the states.

It has been California's experience that the federal government will not represent the state's claims in regard to Medicaid fraud. (See, Declaration of Thomas A. Temmerman, Exhibit B). A decision that the states are preempted from enforcing Medicaid rebate fraud could leave the states without any remedy for losses suffered under the rebate agreements.

In their arguments for preemption in the Montana and Nevada cases, defendants rely heavily on Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341 (2001). This reliance is misplaced. In Buckman, the statute at issue, the Federal Food, Drug, and Cosmetic Act (FDCA) as amended by the Medical Devices Amendments of 1976 (MDA) expressly granted the federal agency at issue, the FDA, sole responsibility for policing fraud against the agency. The conflict in Buckman stemmed "from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and the Agency uses this authority to achieve a delicate balance of statutory objectives that can be skewed by allowing state-law fraud on-the-FDA-claims." Buckman at 348. Unlike the regulation of medical devices at issue in Buckman, the Medicaid program is a joint state-federal program, and the obligation to investigate and prosecute fraud is expressly granted to both the federal government and the states.

## II.

### **THERE IS NO EXPRESS PREEMPTION OF REBATE CLAIMS IN THE FEDERAL REBATE STATUTE**

The Supreme Court has held that preemption may be differentiated into three discrete categories: (1) express preemption, where a federal statute contains "explicit preemptive language;" (2) field preemption, in which the federal regulatory scheme is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it;" and (3) implied conflict preemption, in which "compliance with both federal and state regulations is a physical impossibility" or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Pharmaceutical Research and Manufacturers of America v. Meadows, 304 F.3d at 1205, citing Gade v. National Solid Wastes Mgmt., 505 U.S. 88, 98, 120 L. Ed. 2d 73, 112 S. Ct. 2374 (1992). There is no express preemption in the medicaid statute so the question becomes whether there is field preemption or an implied conflict with respect to the regulation of the rebate fraud.

Since the rebate statute provides for the application of other penalties in addition to those delineated therein, there is no clear intent by Congress for the listed rebate penalties to be exclusive of other remedies in combating fraud with respect to the rebate program. The language clearly undercuts any argument that Congress intended the rebate provisions to preempt state enforcement, especially where the states are a named beneficiary of the rebate agreements and are directly harmed by the fraud.

42 U.S.C.1396r-8 (b)(3)(C)(ii) (Terms of Rebate Agreement; Penalties) provides:

(ii) False information. Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed \$ 100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. . . . (Emphasis added).

This contemplates additional penalties outside of the statute itself. There is no express limitation as to penalties provided by federal law only. Therefore, contrary to defendants' assertions, nothing in the rebate statute suggests that the enforcement tools allocated to the Secretary of Health and Human Services are the only tools available to prosecute fraud in connection with rebates. Questions of statutory interpretation begin by examining the text of the statute to determine whether its meaning is clear. Hughes Aircraft Co. v. Jacobson, 525 U.S. 432, 438, 142 L. Ed. 2d 881, 119 S. Ct. 755 (1999). "In construing a statute we must begin, and often should end as well, with the language of the statute itself." United States v. Steele, 147 F.3d 1316, 1318 (11th Cir. 1998). Here,

the language clearly provides for cooperative effort to investigate and prosecute fraud.

Defendants in the Montana and Nevada cases assert that because HHS has powers to impose fines for failure to properly report pricing data related to rebates, they must have exclusive authority to enforce the fraud statutes regarding Medicaid rebates. There is no statutory or case-law authority for that assumption of exclusivity, however. The mere fact that there are confidentiality protections covering the pricing data that is reported to CMS, does not mean that the data would not be made available to the states where there is evidence of fraud. Also, the confidentiality provision does mention (and covers) the states. 42 U.S.C. 1396r-8(b)(3)(D) provides in part:

(D) Confidentiality of information. Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—

- (i) as the Secretary determines to be necessary to carry out this section,
- (ii) to permit the Comptroller General to review the information provided, and
- (iii) to permit the Director of the Congressional Budget Office to review the information provided.

Additionally, there is no intent indicated from the statute that a privilege would exist with respect to the data where litigation ensues. Generally, there is no absolute federal privilege for trade secret information. The courts may exercise discretion limiting unnecessary disclosure of trade secrets. See Federal Open Market Comm. v. Merrill, 443 U.S. 340, 362, 99 S. Ct. 2800, 2813 (1979). Similarly, under California state law, the trade secret privilege does not apply where allowance of the privilege would conceal fraud or otherwise work injustice. Cal. Evid. Code §1060. Clearly the state would have access to the data in a court proceeding where the data would show that there is evidence of fraud. The argument regarding the secrecy of the pricing data used for rebates does not lead to the

sweeping conclusion that the rebate statute preempts any state enforcement of fraud regarding the rebate agreements. In the rebate program, the states submit the utilization data to CMS for calculation of the rebate amount and the state receives the rebate payments. 42 U.S.C.1396r-8(b)(1)(A). The state then credits the federal government with the federal share of the rebate. 42 U.S.C.1396r-8(b)(1)(B). The state is a direct beneficiary of the rebate agreement and there is no evidence that Congress sought to exclude the states from enforcing their interest in the contract.<sup>2</sup> Although this could not be articulated in open court since the complaint at issue is still sealed, the Court needs to be aware that the Medicaid rebate claims in the California *qui tam* case involve allegations that manufacturers defrauded the Medicaid program by misrepresenting that their drugs were non-innovator drugs (subject to a lower rebate) rather than innovator drugs (subject to higher rebates). Neither access to nor knowledge of specific AMPs or BPs is necessary to allege or to prove these false claims allegations regarding Medicaid rebates.<sup>3</sup>

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<sup>2</sup> As set forth in Section I, above, the entire argument about the secrecy of the pricing dates is inapplicable to any preemption argument concerning California's rebate claims in any event.

<sup>3</sup> The actual AMPs and BPs would only be necessary for the calculation of actual damages, since the effect of imposing innovator rebates on certain of the defendants' drugs would be to calculate the rebate as a larger percentage of AMP or the difference between AMP and BP. The AMPs and BPs could be provided by defendants during discovery, as is common with information necessary to calculate damages. Nothing in the confidentiality provisions concerning AMPs or BPs precludes defendants from producing that information during discovery, as recently occurred during litigation in Texas involving pricing issues.

## III.

**THE REBATE CLAIMS IN THE CALIFORNIA QUI TAM COMPLAINT  
SHOULD BE DISMISSED WITHOUT PREJUDICE AND THE  
CALIFORNIA ACTION SHOULD BE REMANDED**

From the briefing and the oral argument on December 12, 2003, it appeared that the preemption issue on the best price Medicaid rebate claims is largely driven by the confidentiality provision regarding AMPs and BPs that are submitted to the federal government only pursuant to the federal Medicaid rebate contracts that manufacturers sign. In the California *qui tam* case, however, the Medicaid rebate claims do not involve AMPs or BPs, the claims are not related to a federal contract and the confidentiality provisions do not apply here. The Court needs to be aware that the Medicaid rebate claims in the California *qui tam* case involve allegations that manufacturers defrauded the Medicaid program by misrepresenting that their drugs were non-innovator drugs (subject to a lower rebate) rather than innovator drugs (subject to higher rebates). Neither access to nor knowledge of specific AMPs or BPs is necessary to allege or to prove these false claims allegations regarding Medicaid rebates.<sup>4</sup>

Accordingly, a determination by this Court that the confidentiality of AMPs and BPs indicates Congressional intent to preempt those types of Medicaid rebate claims will have little or no bearing on the California rebate claims. Further, the preemption argument based on the existence of a federal

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<sup>4</sup> The actual AMPs and BPs would only be necessary for the calculation of actual damages, since the effect of imposing innovator rebates on certain of the defendants' drugs would be to calculate the rebate as a larger percentage of AMP or the difference between AMP and BP. The AMPs and BPs could be provided by defendants during discovery, as is common with information necessary to calculate damages. Nothing in the confidentiality provisions concerning AMPs or BPs precludes defendants from producing that information during discovery, as recently occurred during litigation in Texas involving pricing issues.

contract, with claims that would be decided under federal common law, is not applicable to the California rebate claims.

### CONCLUSION

For these reasons, there appears to be little reason to defer ruling on California's Motion to Remand pending the Court's resolution of the federal preemption issues in the Montana and Nevada cases. The State of California, joined by relator Ven-A-Care, respectfully requests that its motion for remand be granted, with dismissal without prejudice of the Medicaid rebate claims in the still-sealed complaint. This course of action will appropriately balance the right of the State to bring its claims in a forum of its choice, in one or more actions as would normally be its choice.

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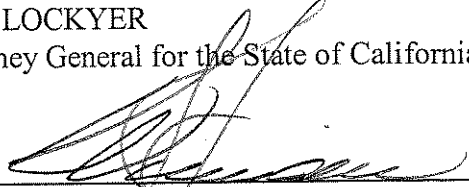
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Based on the foregoing, California respectfully requests that the Court not conclude that the federal statute preempts any state enforcement of fraud regarding the rebate agreements.

Dated: December 18, 2003.

Respectfully submitted,

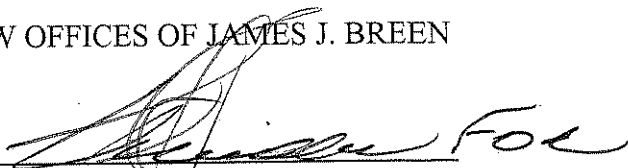
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